Best Practice: Creating Flu Vaccine

CALYX.AI

1 Revision History

When Calyx releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Calyx reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Calyx recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/Revision Date	Summary of Change(s)
v7.0	30-Apr-2021	Update Best Practice for v7.0 – No Impact
N/A	22-Mar-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	21-Oct-2020	Update Best Practice for v6.2 CHF6 – No Impact
v6.2 CHF5	03-Aug-2020	Update Best Practice for v6.2 CHF5 – No Impact
v6.2 CHF4	28-Feb-2020	Update Best Practice for v6.2 CHF4 – No Impact
v6.2 CHF3	27-Jun-2019	Update Best Practice for v6.2 CHF3 – No Impact
v6.2 CHF2	15-Feb-2019	Update Best Practice for v6.2 CHF2 – No Impact

2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice guide defining the process of capturing seasonal ‘flu products in Calyx RIM (i.e. those ‘flu products where strans may change through the life of the product).

3.1 Scope

The scope of the process is for capturing Flu Strains in Calyx RIM for Registrations.

4 Flu Vaccine Product Families

When defining a Flu Vaccine Product Family, most of the same rules apply as with Pharmaceutical Product Families. At the Product Family level substitute Active Ingredients (AI) with an AI Placeholder that will be used to represent each strain included in the Flu Product. The representative Placeholders are assigned rather than the specific Flu Strain itself to allow for the required strain updates.

In Data Administration, the Substance Type is defined as Placeholder; the actual strains are also captured in the Substances Data Administration with the Substance Type of Strain. The association of the Strain (and the name of any derived strain) to the Placeholder and the capturing of its concentration is described in the Active Ingredient, Flu Strain Detail in the Product Detail Set.

5 Data Administration Activities

5.1 Substance

1. A new Substance should be created for each required ‘flu strain:
   - ***Substance Name***: <as required by your organisation>
   - ***Substance Type***: Placeholder
2. A new substance should be created for each actual ‘flu strain:
   - **Substance Name**: <as required> (e.g. A/Brisbane/10/2007 (H3N2))
   - **Substance Type:** Strain

6 Flu Process

1. A Product Family should be created with the following attributes:
   - **Product Family Name**: <as required by your organisation>
   - **Product Family Type**: Flu Vaccine
   - **Active Ingredient**: associate all required Placeholder Active Ingredients
   - Complete other fields as required by your organisation
2. A Product should be created
   - **Product Name:** <as required by your organisation>
   - Complete other fields as required by your organisation

3. A Component should be created
   - **Component Name:** <as required by your organisation>
   - **Component Type**: Flu Vaccine
   - **Active Ingredient**: <associate all required for this component>
   - Complete other fields as required by your organisation
   - Note the concentrations and Active Ingredients of each strain will be captured in the Product Detail Set
4. A Product Detail Set template may be created (Note: the same steps would be required for a Product Detail Set associated with an Application)
   - **Product Detail Set Name:** <as required by your organisation>
   - Complete other fields as required by your organisation
5. Associate Active Ingredients to Product Detail Set template
   - Right mouse click on the Active Ingredient Node
   - Select 'Add Active Ingredient'
6. Capture Active Ingredient Details
   - **Active Ingredient Name**: select each Active Ingredient (placeholder) in turn.
   - Complete other fields as required by your organisation
7. Associate 'Flu strains to each Active Ingredient Placeholder
   - Right mouse click on the Placeholder name
   - Select 'Add 'Flu strain'
8. Capture 'Flu Strain details
   - **Flu Strain Name**: select strain as required in turn.
   - Complete other fields as required by your organisation

7 Maintenance of Flu Products

When the annual ‘flu changes are defined, the PDS gets updated rather than the Active Ingredient(s) on the Product Family:

1. Identify and/or create the new Flu Strain in Data Administration.
2. Create an Event with associated PDS.
3. Withdraw any strain that is being replaced.
4. Add the new Flu Strain for as required.
5. Follow standard processes for Submitting and Approving the Event.